 K112629

OCT 11 2011

4. 510(k) Summary according to 807.92

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Onset Medical Corporation is providing the summary of Substantial Equivalence for the Onset Access Catheter System.

4.1 Sponsor /Applicant Name and Address

Onset Medical Corporation
13900 Alton Parkway
Suite 120
Irvine, CA 92618

4.2 Sponsor Contact Information

Joseph Bishop
President, CEO
Onset Medical Corporation
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4.3 Date of Preparation of 510(k) Summary

September 8, 2011

4.4 Device Trade or Proprietary Name

Onset Access Catheter System

4.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY)

4.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Name of Manufacturer (Town, State)	510(k) Number
Reverse RePort™ Guide Catheter System	Reverse Medical Corporation Irvine, CA 92618	K102418

4.7 Device Description

The Onset Access Catheter System is a two-catheter system comprised of a Sheath and a Dilator. The Sheath has a distal region which expands when the Dilator is advanced. The Onset Access Catheter System can be used with hydrophilic guidewires up to.038 inches in diameter to access the desired anatomy.

The proximal ends of the Sheath and the Dilator have a luer fitting to allow attachment of accessories and infusion of liquids through the catheter. The catheter is offered in various sizes to accommodate physician preferences and patient anatomy. A split sheath is provided in the package to provide support and facilitate the introduction of the Sheath's distal expandable region into the catheter introducer sheath. The Catheter System is provided sterile, non-pyrogenic, and is intended for single use only.

4.8 Intended Use

The Onset Access Catheter System is indicated for the introduction of interventional/diagnostic devices into the peripheral, coronary and neuro vasculature.

4.9 Comparison to Predicate Devices

	Onset Access Catheter System	**RePort™ Guide Catheter System**
510(k) Number	TBD	K102418
Classification	SAME	Class II, DQY
Indication	SAME	The RePort Catheter is indicated for the introduction of interventional / diagnostic devices into the peripheral, coronary, and neuro vasculature.
Material		
- Shaft Materials	SAME	PTFE lined nylon/polyurethane with stainless steel and nitinol braid support
- Proximal End Configuration	SAME	Luer Hub
- Radiographic markers / Radiopacity	SAME	• Sheath: Platinum/tungsten bands embedded at junction of expandable section; gold marker at tip of expandable section; • Dilator: shaft is radiopaque throughout
- Packaging	SAME	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton
Sterilization	SAME	EtO

4.10 Summary of Non-clinical Data

4.10.1 Biocompatibility and Sterilization

The Onset Access Catheter System is classified as Externally Communicating Devices, Circulating Blood, Limited Contact (≤ 24 hours). Results of testing demonstrate that the blood contacting materials are biocompatible.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1 guidelines "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The Catheter System successfully passed all of the following biocompatibility tests:

Test	Method
Cytotoxicity	L929 MEM Elution Test
Sensitization	Kligman Maximization
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test
Haemocompatibility	Complement Activation
	Hemolysis
	Inactivated Partial Thromboplastin Time Test
	In vivo thrombogenicity
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

4.10.2 Design Verification (Bench-Top Testing)

The physical, mechanical and performance testing of the Catheter System demonstrated that the product is substantially equivalent to currently marketed predicate devices. Design Verification testing was conducted to evaluate the physical and mechanical properties of the Catheter System. All testing was performed on units which were twice sterilized and met all inspection criteria. Tests on the Catheter System included:

Verification and Test Summary

Bench Tests	**Result**
Dimensional and Visual Inspection	Met established criteria
Guidewire Compatibility	Met established criteria
Torque Response	Met established criteria
Torque Strength	Met established criteria
System Deployment Cycle Test	Met established criteria
Kink Resistance	Met established criteria
Flexibility Test	Met established criteria
Tensile Strength	Met established criteria
Catheter Leak Test (Liquid Leakage)	Met established criteria
Catheter Leak Test (Air Leakage)	Met established criteria
Dynamic Pressure Test	Met established criteria
Static Burst Test	Met established criteria
Aspiration Test	Met established criteria
Hub Gauging	Met established criteria
Corrosion Resistance	Met established criteria
USP Particulate Test	Met established criteria
Navigation and Accessibility Capabilities *in vitro*	Met established criteria
***In vivo* Tests**	**Result**
System Deliverability, Compatibility, Visibility and Aspiration Performance	Met established criteria
Acute histopathology of treated vessels	Met established criteria
Biocompatibility testing	Met established criteria

The physical, mechanical and performance testing of the subject Catheter System demonstrated that the product is safe and effective for its labeled indications and is Substantially Equivalent to currently marketed predicate devices.

4.11 Substantial Equivalence

The Onset Access Catheter System is the same device as the RePort™ Guide Catheter System. The only difference is that it is manufactured and marketed by Onset Medical rather than Reverse Medical. Therefore, it is equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate device.

The data presented in K102418 demonstrated that the RePort™ Guide Catheter System was safe and effective for its labeled indications and Substantially Equivalent to currently marketed predicate devices. The Onset Access Catheter is the same Catheter System and is, therefore, also safe and effective for its labeled indications and Substantially Equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 11 2011

Onset Medical Corporation
c/o Mr. Joseph Bishop
President, CEO
13900 Alton Parkway
Suite 120
Irvine, CA 92618

Re: K112629
Trade Name: Onset Access Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: II (two)
Product Code: DQY
Dated: September 7, 2011
Received: September 9, 2011

Dear Mr. Bishop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

3. Indications for Use

510(k) Number (if known): K112629

Device Name: Onset Medical Access Catheter System

Indications for Use:

The Onset Medical Access Catheter System is indicated for the introduction of interventional/diagnostic devices into the peripheral, coronary and neuro vasculature.

Prescription Use X AND/OR Over the Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112629